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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,342	01/26/2001	Mark G. Fleischhacker	058442/9191	6291

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MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,342

Applicant(s)

FLEISCHHACKER, MARK G.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,7. 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the core wire comprising multiple helically-wound, non-metallic fibers of claims 19-22 and the core wire comprising a single helically-wound non-metallic fiber of claims 23-24 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:
- a. On page 4, line 21, "is" apparently should be deleted.
 - b. On page 7, line 7, --is-- apparently should be inserted before "polyetheretherketone".
 - c. On page 10, line 18, "Pebax" apparently should read --PEBAX--.
 - d. On page 15, line 4, "of" apparently should read --or--.

Appropriate correction is required.

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or

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other form of browser-executable code. See MPEP § 608.01. The hyperlink is located at page 7, line 11.

Claim Objections

4. Claim 4 is objected to because of the following informalities: in line 3, “guide” apparently should read --core--. Appropriate correction is required.

5. Claim 5 is objected to because of the following informalities: in line 2, “medal” apparently should read --medial--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim recites that the “fibers are wound to no more than 10 helices per foot”. This limitation contradicts the disclosure of the specification that recites that “the helically wound guide wire body has at least 10 helical turns per foot” at page 8, lines 14-15. One having ordinary skill in the art would not be enabled to make the core wire claimed in claim 22 because the range of helices claimed is outside the range set forth in the specification.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "the polyetherimide coating" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There is no polyetherimide coating recited in claim 10 prior to this recitation.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Osborne. Osborne teaches a wire guide including a core wire having multiple, helically-wound non-metallic fibers and a binder resin that is dispersed between the fibers so as to fill any void space therebetween and a coil wire disposed about the distal segment (claims 1-3).

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12. Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. Wang et al. teaches a wire guide including a core wire having a single, helically-wound non-metallic fibers and a binder resin that is dispersed between the fibers so as to fill any void space therebetween and a coil wire disposed about the distal segment.

13. Claims 1-12 and 16-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Cordis Corporation et al. Cordis Corporation et al. teach a guide wire including a core wire comprising a non-metallic, non-woven material. The core wire may be tapered such that the diameter of a distal section is smaller and more flexible than medial and proximal sections of the core wire. The diameters of the distal, medial and proximal sections of the core wire may otherwise be substantially the same. A hydrophilic, polymeric coating covers the length of the core wire (claim 17). The core wire is constructed of a polymeric material and is covered with a second polymeric material. The core wire may also comprise reinforcing carbon fibers (claim 11).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne in view of Sicurelli, Jr. et al. Osborne teaches all of the limitations of the claims, including that the non-

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metallic fibers comprise carbon, except that the binder resin comprises vinyl ester. Sicurelli, Jr. et al. teach that it is known in the medical arts to use vinyl ester resins to bind medical grade fibers for various purposes (col. 9, lines 1-5). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use a vinyl ester resin to bind the carbon fibers of Osborne in view of the teachings of Sicurelli, Jr. et al. as a design choice, merely substituting one known type of binder resin for another.

16. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cordis Corporation et al. in view of Munsinger et al. Cordis Corporation et al. teach all of the limitations of the claims except that the core wire comprises polyetheretherketone. Munsinger et al. teach that it is known in the medical arts to use polyetheretherketone to construct guide catheters because the material is sturdy and inexpensive. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use a polyetheretherketone to make a core wire similar to that of Cordis Corporation et al. in view of the teachings of Munsinger et al. as a design choice, merely substituting one known material of construction for another that is known to be sturdy and inexpensive.

17. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cordis Corporation et al. in view of Palermo et al. Cordis Corporation et al. teach all of the limitations of the claims except that the core wire is coated with PEBAX polyetherimide. Palermo et al. teach that it is known in the medical arts to coat guide wire cores with PEBAX polyetherimide to lubricate the guide wire in order to enhance the suitability of the guide wire for use within

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catheters and vascular lumen. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use PEBAX polyetherimide to coat a core wire similar to that of Cordis Corporation et al. in view of the teachings of Palermo et al. as a design choice, merely substituting one known material of construction for another that is known to enhance the suitability of the guide wire for use within catheters and vascular lumen.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cordis Corporation et al. in view of Munsinger et al. as applied to claim 13 above, and further in view of Palermo et al. Cordis Corporation et al. and Munsinger et al. teach all of the limitations of the claims except that the core wire is coated with PEBAX polyetherimide. Palermo et al. teach that it is known in the medical arts to coat guide wire cores with PEBAX polyetherimide to lubricate the guide wire in order to enhance the suitability of the guide wire for use within catheters and vascular lumen. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use PEBAX polyetherimide to coat a core wire similar to that of Cordis Corporation et al. and Munsinger et al. in view of the teachings of Palermo et al. as a design choice, merely substituting one known material of construction for another that is known to enhance the suitability of the guide wire for use within catheters and vascular lumen.


Conclusion


19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Berg et al. teach a braidless guide catheter. Stoy et al. teach polymeric guidewires with lubricious surfaces. Jacobsen et al. teach a hybrid tubular guide wire for catheters.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Charles A. Marmor, II
Examiner
Art Unit 3736


CAM
May 20, 2002